



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 29 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Cynthia C. Knapp
Director Lab Services
TREK Diagnostic Systems, Inc.
29299 Clemens Road, Suite 1-K
Westlake, OH 44145

Re: k032382
Trade/Device Name: Sensititre[®] *Haemophilus/Streptococcus pneumoniae* (HP) MIC
Plates
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY, LRG
Dated: July 28, 2003
Received: August 1, 2003

Dear Ms. Knapp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

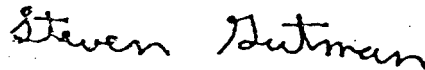
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If known): K032382

Device Name: Haemophilus / Streptococcus pneumoniae (HP) MIC Susceptibility plate

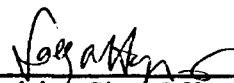
Indications For Use:

The ~~Sensitive~~ Haemophilus / Streptococcus pneumoniae (HP) MIC Susceptibility plate is an *in vitro* diagnostic product for clinical susceptibility testing of Haemophilus / Streptococcus pneumoniae.

This 510(k) is for the addition of Gemifloxacin in the dilution range of 0.001 - 16 µg/ml to the Sensititre Haemophilus / Streptococcus pneumoniae (HP) MIC Susceptibility plate MIC panel for testing Haemophilus / Streptococcus pneumoniae isolates. The approved primary "Indications for Use" and clinical significance of Gemifloxacin is for: Streptococcus pneumoniae and Haemophilus Influenzae.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 8/28/03
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032382

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐